

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

**TRUTEK CORP.,**

Plaintiff,

**v.**

**Case No. 2:21-cv-10312**

**BLUEWILLOW BIOLOGICS, INC.;  
ROBIN ROE 1 through 10, gender  
neutral fictitious names, and; ABC  
CORPORATION 1 through 10  
(fictitious names).**

**Hon. Stephen J. Murphy, III  
Mag. R. Steven Whalen**

**JURY TRIAL DEMANDED**

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW  
BIOLOGICS, INC.'S ANSWER, AFFIRMATIVE DEFENSES,  
COUNTERCLAIM, AND JURY DEMAND**

Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. (“Defendant” or “BlueWillow”), by and through its undersigned counsel, submit the following Answer, Affirmative Defenses, and Counterclaims to Plaintiff/Counter-Defendant Trutek Corp.’s Complaint (“Plaintiff” or “Trutek”):

**BLUE WILLOW BIOLOGICS, INC.’S ANSWER TO COMPLAINT**

**PARTIES<sup>1</sup>**

1. Plaintiff, TRUTEK CORP. (“TRUTEK”) is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.

**ANSWER:** BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1 of Plaintiff’s Complaint and therefore denies them.

2. Upon information and belief, Defendant, BlueWillow Biologics, Inc. (“BLUEWILLOW”) is a corporation of the State of Delaware, with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

**ANSWER:** BlueWillow admits that it is a corporation organized and existing under the laws of Delaware with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

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<sup>1</sup> BlueWillow repeats the headings contained in the Complaint for reference only and their inclusion herein should not be interpreted as any admission or acquiescence as to the statements contained therein.

### **FEDERAL SUBJECT MATTER JURISDICTION**

3. The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331 concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271.

**ANSWER:** Paragraph 3 of Plaintiff's Complaint states legal conclusions to which no response is required. To the extent any response may be required BlueWillow admits that Trutek purports to bring this action under 28 U.S.C. § 1331, the Patent Laws of the United States, 28 U.S.C. §§ 1338(a), (b), and 35 U.S.C. § 271. To the extent further averments in Paragraph 3 are not addressed by the foregoing, BlueWillow denies as untrue the allegations contained in Paragraph 3 of Plaintiff's Complaint.

### **IN PERSONAM JURISDICTION**

4. The *in personam* jurisdiction of this Court over Defendant BLUEWILLOW is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in Michigan and BLUEWILLOW has an established place of business in Michigan.

**ANSWER:** The allegations of Paragraph 4 of Plaintiff's Complaint appear to be directed to whether the Court has personal jurisdiction over BlueWillow, which is a legal conclusion to which no response is required. BlueWillow does not contest personal jurisdiction for the purposes of this action. To the extent further averments in Paragraph 4 are not addressed by the foregoing, BlueWillow denies as untrue the allegations contained in Paragraph 4 of Plaintiff's Complaint.

## **VENUE**

5. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of Michigan, and Defendant BLUEWILLOW has an established place of business thereat, and which is furthermore located within the venue of the Eastern District of Michigan.

**ANSWER:** The allegations of Paragraph 5 of Plaintiff's Complaint appear to be directed to whether venue is proper in this judicial district, which is a legal conclusion to which no response is required. BlueWillow does not contest venue for the purposes of this action. BlueWillow admits that it has an established place of business located within the Eastern District of Michigan. To the extent further averments in Paragraph 5 are not addressed by the foregoing, BlueWillow denies as untrue the allegations contained in Paragraph 5 of Plaintiff's Complaint.

## **STATEMENT OF FACTS AND CAUSES OF ACTION**

6. Ashok Wahi ("WAHI") is President of Plaintiff TRUTEK.

**ANSWER:** BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 6 of Plaintiff's Complaint and therefore denies them.

7. On November 21, 1995, United States Patent No. 5,468,488 (hereinafter the '488 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Application Product and Method." The '488 Patent was assigned to TRUTEK.

**ANSWER:** BlueWillow admits that the face of United States Patent No. 5,468,488 identifies it as being issued on November 21, 1995 with a title of

“Electrostatically Charged Nasal Application Product and Method.” BlueWillow admits that WAHI is listed on the face of the ’488 patent as the named inventor. BlueWillow otherwise denies as untrue the allegations contained in Paragraph 7 of Plaintiff’s Complaint.

8. On October 7, 1997, United States Patent No. 5,674,481 (hereinafter the ’481 Patent) was issued to WAHI for his invention titled, “Electrostatically Charged Nasal Topical Application Product.” The ’481 Patent was assigned to TRUTEK.

**ANSWER:** BlueWillow admits that the face of United States Patent No. 5,674,481 identifies it as being issued on October 7, 1997 with a title of “Electrostatically Charged Nasal Topical Application Product.” BlueWillow admits that WAHI is listed on the face of the ’481 patent as the named inventor. BlueWillow otherwise denies as untrue the allegations contained in Paragraph 8 of Plaintiff’s Complaint.

9. On January 18, 2005, United States Patent No. 6,844,005 (hereinafter the ’005 Patent) was issued to WAHI for his invention titled, “Electrostatically Charged Nasal Application Product With Increased Strength.” The ’005 Patent was assigned to TRUTEK.

**ANSWER:** BlueWillow admits that the face of United States Patent No. 6,844,005 identifies it as being issued on January 18, 2005 with a title of “Electrostatically Charged Nasal Application Product With Increased Strength.” BlueWillow admits that WAHI is listed on the face of the ’005 patent as the named inventor. BlueWillow otherwise denies as untrue the allegations contained in Paragraph 9 of Plaintiff’s Complaint.

10. On April 24, 2012, United States Patent No. 8,163,802 (hereinafter the '802 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Multi-Acting Nasal Application Product, and Method," on a patent application that was filed at the United States Patent and Trademark Office (USPTO) on May 16, 2009. The '802 Patent was assigned to TRUTEK. The '802 Patent is attached hereto as Exhibit 6.

**ANSWER:** BlueWillow admits that the face of United States Patent No. 8,163,802 identifies it as being issued on April 24, 2012 with a title of "Electrostatically Charged Multi-Acting Nasal Application, Product, and Method," based on a patent application filed on May 16, 2009. BlueWillow admits that WAHI is listed on the face of the '802 patent as the named inventor. BlueWillow otherwise denies as untrue the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. The patented technology made it possible for people to apply TRUTEK's manufactured products in and around their nasal passages to reduce reactions to airborne allergens and to reduce or eliminate reactions to viral infections from influenza and the common cold by restricting and inactivating virus sized particles. This is done by establishing an electrostatic charge in and around nasal passages.

**ANSWER:** BlueWillow denies that any of the patents identified in Plaintiff's Complaint solved any asserted problem. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 11 of Plaintiff's Complaint and therefore denies them.

12. As of the year 1992 going forward, TRUTEK utilized its patented and proprietary trade secret technology to establish proof of concept, develop, formulate, manufacture, sell, and/or license over-the-counter products under the brand name NasalGuard® AllergieBlock®, NasalGuard Cold&Flu Block®, NasalGuard® Multi Acting™, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks® Skin and Truteks® skin care products, along with electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patents and Pending Patent Applications, also including products under the brand names Chloraseptic Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, further including but not limited to nasal application product lines such as gels, pre-moistened products for *e.g.* applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, and multi-acting/integrated products.

**ANSWER:** BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 12 of Plaintiff's Complaint and therefore denies them.

13. Claim 1 of the '802 Patent claims a method of applying a formulation to the skin or tissue of a person's nasal passages in a thin film. The formulation attracts and holds particulate matter to the thin film, and binds it to the thin film. The bound particulate matter is then inactivated by at least one ingredient that renders it harmless. One such claimed inactivating ingredient is benzalkonium chloride (claim 7). This process is sometimes referred to as "catch, hold, and kill."

**ANSWER:** Paragraph 13 of Plaintiff’s Complaint states legal conclusions to which no response is required. The cited patent speaks for itself and therefore no further response is required. To the extent further averments in Paragraph 13 are not addressed by the foregoing, BlueWillow denies as untrue the allegations contained in Paragraph 13 of Plaintiff’s Complaint.

14. According to information and belief, sometime in 2020, Defendant BLUEWILLOW manufactured and marketed one or more over-the-counter pharmaceutical products named NanoBio<sup>®</sup> Protect (“NANO BIO”). According to information and belief, the NANO BIO products were sold over-the-counter at least at CVS pharmacies nationwide, and were sold online to customers by [Amazon.com](https://www.amazon.com).

**ANSWER:** BlueWillow admits that it manufactured and marketed NanoBio<sup>®</sup> Protect starting in April 2020 and that NanoBio<sup>®</sup> Protect was sold over-the counter at CVS and on Amazon.com. BlueWillow otherwise denies as untrue the remaining allegations in Paragraph 14 of Plaintiff’s Complaint.

15. BLUEWILLOW’s website advertises the NANO BIO product being applied to a customer’s nasal passages. Their product forms positively charged “NanoBio Droplets” that are approximately 600 nanometers<sup>1</sup> in size, which adhere to nasal membranes. Most harmful particles, such as bacteria or viruses (referred to as “germs”), are negatively charged. The positively charged “NanoBio Droplets” attract and bind to these particles. The NANO BIO product formulation contains benzalkonium chloride (which the website calls BZK) that adheres to the surface of the “NanoBio droplets.” According to the website, the “NanoBio droplets” surround the germs and “kill them via membrane disruption.” (See Exhibit 1 attached hereto.) The NANO BIO product implements the methodology of “catch, hold, and kill.” The



NANOBIO website “Frequently Asked Questions” section (Exhibit 2) describing the product further enforces this mechanism of action.

**ANSWER:** BlueWillow admits that NanoBio<sup>®</sup> Protect incorporates the active ingredient benzalkonium chloride (BZK). BlueWillow further admits that a document purporting to be a printout from the NanoBio<sup>®</sup> Protect website is attached as Exhibit 1, and that a document purporting to be a printout of the “Frequently Asked Questions” section of the NanoBio<sup>®</sup> Protect website is attached as Exhibit 2. BlueWillow otherwise denies as untrue the allegations of Paragraph 15 of Plaintiff’s Complaint.

16. Sometime in 2020, WAHI suspected that the NANOBIO product infringes one or more of TRUTEK’s patents. To that end, on June 23, 2020, TRUTEK personnel purchased the NANOBIO product from [Amazon.com](https://www.amazon.com). After extensive in-house experimentation, it was indicated that the NANOBIO product functions by producing an electrostatic charge in and around the user’s nasal passages. It was indicated that NANOBIO product infringes claims of TRUTEK’s ’802 Patent. On January 14, 2021, TRUTEK personnel purchased a NANOBIO product from CVS, and obtained similar results through in-house experimentation.

**ANSWER:** BlueWillow denies that NanoBio<sup>®</sup> Protect infringes any valid and enforceable claim of the ’802 Patent and further denies that NanoBio<sup>®</sup> Protect functions by producing an electrostatic charge in and around the user’s nasal passages. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 16 of Plaintiff’s Complaint and therefore denies them.

17. To validate TRUTEK's in-house experimental results, TRUTEK contracted with Alexai Ermakov, Ph.D. to compare the electrostatic charges between BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® products. His experiments showed not only that the NANOBIO product exhibited a surface electrostatic charge, but also that the orders of magnitude of the charges of the BLUEWILLOW and TRUTEK products were of the same order of magnitude. Dr. Ermakov's Report is attached hereto as Exhibit 3. For further verification, TRUTEK contracted with Electro-Tech Systems ("ETS") in Perkasi, Pennsylvania, to run additional experiments. ETS personnel applied BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® product to pig skin swatches. Pig skin is very similar to human skin tissue. The ETS and Ermakov experiments yielded similar results. The NANOBIO product exhibited a surface electrostatic charge of the same order of magnitude as the NasalGuard® product. The ETS report is attached hereto as Exhibit 4.

**ANSWER:** BlueWillow denies that NanoBio® Protect infringes any valid and enforceable claim of the '802 Patent and further denies that NanoBio® Protect functions by producing an electrostatic charge in and around the user's nasal passages. BlueWillow admits that documents purporting to be copies of reports are attached as Exhibits 3 and 4, but denies the substance of the reports. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 17 of Plaintiff's Complaint and therefore denies them.

18. On January 31, 2021, Keith Altman, a resident of the State of Michigan, ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online from

[Amazon.com](https://www.amazon.com). The product was to be shipped by [Amazon.com](https://www.amazon.com) to his address in Michigan. Mr. Altman used his computer to place the order, and the computer is located in Michigan, and it was located therein at the time that he placed his order. On February 1, 2021, Mr. Altman received the ordered one unit of NanoBio Protect Nasal Antiseptic in Michigan at the designated Michigan shipping address. A declaration of Keith Altman attesting to these events is attached hereto as Exhibit 5.

**ANSWER:** BlueWillow admits that a document purporting to be a copy of a Declaration of Keith Altman is attached as Exhibit 5. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 18 of Plaintiff's Complaint and therefore denies them.

19. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages was disclosed in TRUTEK's '488, '481, '005, and '802 Patents. A copy of the '802 Patent is attached hereto as Exhibit 6.

**ANSWER:** BlueWillow admits that a document purporting to be a copy of the '802 Patent is attached as Exhibit 6. The remainder of Paragraph 19 of Plaintiff's Complaint states legal conclusions to which no response is required. The cited patents speak for themselves and therefore no further response is required. To the extent further averments in Paragraph 19 are not addressed by the foregoing, BlueWillow denies as untrue the allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages is inherent in TRUTEK's

formulations and manufacturing processes. Efficacy studies show that TRUTEK's methodology presented a viable solution to relief of allergy, cold, and flu symptoms.

**ANSWER:** BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 20 of Plaintiff's Complaint and therefore denies them.

21. Upon information and belief, just as TRUTEK's products work on allergens and viruses by creating an electrostatic charge around nasal passages and further inactivate said allergens and viruses, the NANOBIO products work the same way.

**ANSWER:** BlueWillow denies that NanoBio® Protect functions or works in the same manner as Trutek's products. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 21 of Plaintiff's Complaint and therefore denies them.

22. The NANOBIO products are sold to customers by [Amazon.com](https://www.amazon.com) as are TRUTEK's competing products also sold thereby. The competitive sales of the competing NANOBIO products deprive TRUTEK of sales and profits from its own products.

**ANSWER:** BlueWillow denies that Trutek's products are "competing products" to NanoBio® Protect and that the sale of NanoBio® Protect has deprived Trutek of any sales and/or profits from its own products. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 22 of Plaintiff's Complaint and therefore denies them.

23. Upon information and belief, Defendants Robin Roe 1 through 10 and ABC Corporations 1 through 10 also infringe on the claims of TRUTEK's '802 Patent.

**ANSWER:** BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 23 of Plaintiff's Complaint and therefore denies them.

### **GENERAL ALLEGATIONS**

24. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

**ANSWER:** BlueWillow incorporates and re-alleges its answers to Paragraphs 1 through 23 of Plaintiff's Complaint.

25. Plaintiff owns intellectual property related to certain formulations based upon attracting and/or repelling electrostatically charged particles in and around a person's nasal passages by application of a product that maintains an electrostatic charge on the skin or mucous membranes. Plaintiff has expended considerable resources to inventing, formulating, and developing its inventions and products and to protecting its rights therein. Plaintiff holds all rights, title, and interest to its '488, '481, '005, and '802 Patents. The '802 Patent is in full force and effect. TRUTEK is the legal owner of the '802 Patent and possesses all rights of recovery under the patent.

**ANSWER:** BlueWillow denies that any intellectual property purportedly owned by Trutek solved any asserted problem. BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 25 of Plaintiff's Complaint and therefore denies them.

## COUNT I – INFRINGEMENT OF THE '802 PATENT

26. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

**ANSWER:** BlueWillow incorporates and re-alleges its answers to Paragraphs 1 through 25 of Plaintiff's Complaint.

27. Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the '802 patent.

**ANSWER:** Paragraph 27 of Plaintiff's Complaint states legal conclusions to which no response is required. The cited patent speaks for itself and therefore no further response is required. To the extent further averments in Paragraph 27 are not addressed by the foregoing, BlueWillow lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 27 of Plaintiff's Complaint and therefore denies them.

28. Defendants distribute, make, use, offer to sell and/or sell infringing products, *i.e.*, the NANOBIO products.

**ANSWER:** BlueWillow denies as untrue the allegations of this paragraph.

29. Defendants distribute, make, use, offer to sell and/or sell infringing products, *i.e.*, the NANOBIO products, which infringe on the '802 Patent, without authority or license from Plaintiff.

**ANSWER:** BlueWillow denies as untrue the allegations of this paragraph.

30. Defendants infringe at least claims 1, 2, and 7 of the '802 Patent because the NANOBIO products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide.

**ANSWER:** BlueWillow denies as untrue the allegations of this paragraph.

31. Plaintiff has been damaged as a result of Defendants' infringement of the '802 Patent, and will continue to be damaged unless such infringement is enjoined by this Court pursuant to 35 U.S.C. § 283.

**ANSWER:** BlueWillow denies as untrue the allegations of this paragraph.

32. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate in an amount not less than a fair and reasonable royalty.

**ANSWER:** BlueWillow denies as untrue the allegations of this paragraph.

### **PLAINTIFF'S PRAYER FOR RELIEF**

BlueWillow denies that it is liable for any relief requested in Plaintiff's Prayer for Relief, including the relief requested in subparagraphs 1–5. BlueWillow is not infringing and has never infringed, willfully or otherwise, any valid and enforceable claim of the '802 Patent in any manner, including directly or indirectly, either literally or under the doctrine of equivalents. Plaintiff is not entitled to any damages, including but not limited to damages in the form of a reasonable royalty, lost profits, enhanced damages under 35 U.S.C. § 284, supplemental damages for alleged post-verdict infringement, pre-judgment or post-judgment interest, or costs. Plaintiff is not entitled to any injunctive relief. Plaintiff's Prayer for Relief should be denied in its entirety.

### **DEMAND FOR DISCOVERY OF INSURANCE COVERAGE**

BlueWillow objects to this request on grounds that a "demand for discovery of insurance coverage" is not a proper element of a complaint under the Federal Rules of Civil Procedure. To the extent a response is required, BlueWillow states that, to the extent any such information is required to be disclosed, BlueWillow will

comply with any applicable disclosure requirements under the Federal Rules of Civil Procedure and any scheduling orders issued by the Court.

### **DEMAND FOR A JURY TRIAL**

BlueWillow concurs in Plaintiff's demand for a jury trial. Pursuant to Federal Rule of Civil Procedure 38(b), BlueWillow hereby demands a jury trial on all issues triable by a jury.

### **BLUEWILLOW BIOLOGICS, INC.'S AFFIRMATIVE DEFENSES**

BlueWillow asserts the following Affirmative Defenses. BlueWillow reserves all affirmative defenses set forth in Federal Rule of Civil Procedure 8(c), under the patent laws of the United States, and any other defenses, at law or in equity, that may now exist or in the future be valid based on discovery and further investigation in this action. No allegation or assertion of a defense is an admission regarding the Parties' respective burden of proof.

#### **FIRST AFFIRMATIVE DEFENSE: FAILURE TO STATE A CLAIM**

1. The Complaint, and its purported cause of action, fails to state facts sufficient to constitute a cause of action against BlueWillow.
2. The allegations contained in the Complaint, or any purported cause of action therein, fail to state any claim upon which relief can be granted.



**SECOND AFFIRMATIVE DEFENSE:  
NO INFRINGEMENT**

3. BlueWillow does not directly or indirectly infringe, and at all relevant times to this action, has not directly or indirectly infringed, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '802 patent.

**THIRD AFFIRMATIVE DEFENSE:  
INVALIDITY**

4. The claims of the '802 patent are invalid, including for, among other reasons, failure to meet one or more of the requisite requirements and/or conditions for patentability in 35 U.S.C. §§ 101, 102, 103 and 112.

**FOURTH AFFIRMATIVE DEFENSE:  
MARKING**

5. On information and belief, BlueWillow's claim for damages is statutorily barred and/or limited by 35 U.S.C. § 287 as, among other reasons, Plaintiff and/or their prior owners of the asserted patent and/or their agents, representatives, and/or licensees failed to adequately mark patented articles.

**FIFTH AFFIRMATIVE DEFENSE:  
ESTOPPEL**

6. On information and belief, BlueWillow's claims are barred by reason of prior art and/or statements and representations made to and by the U.S. Patent and Trademark Office during prosecution of the application that led to the issuance of the '802 patent. Plaintiff is estopped from asserting that the '802 patent claims can

be construed as covering, either literally or under the doctrine of equivalents, any products manufactured, used, imported, sold, or offered for sale by BlueWillow or methods used by BlueWillow.

**SIXTH AFFIRMATIVE DEFENSE:  
UNCLEAN HANDS**

7. On information and belief, Plaintiff has engaged in conduct that constitutes, among other things, fraud and bad faith toward BlueWillow and related to the subject matter of the litigation. Plaintiff is barred under principles of equity from asserting a patent infringement claim against BlueWillow, collecting damages, and obtaining equitable relief, including injunctive relief.

**BLUEWILLOW BIOLOGICS, INC.'S COUNTERCLAIMS**

Defendant/Counter-Plaintiff BlueWillow Biologics, Inc., for its Counterclaims for declaratory judgments of non-infringement and invalidity of U.S. Patent No. 8,163,802 (“the ’802 Patent”) against Plaintiff/Counter-Defendant Trutek Corp., alleges as follows:

**PARTIES**

1. On information and belief, Plaintiff/Counter-Defendant Trutek Corp. (“Plaintiff” or “Trutek”) is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.

2. Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. (“Defendant” or “BlueWillow”) is a corporation of the State of Delaware with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

### **JURISDICTION AND VENUE**

3. This Court has subject matter jurisdiction over BlueWillow’s Counter-Complaint and Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

4. An actual case and controversy exists concerning the alleged infringement and invalidity of the ’802 Patent.

5. Personal jurisdiction and venue are proper in this District pursuant to 28 U.S.C. § 1391 and 1400(b).

### **FACTUAL BACKGROUND**

6. BlueWillow is a clinical-stage biopharmaceutical company focused on developing a new generation of safe and effective intranasal vaccines for challenging respiratory infections, sexually transmitted diseases, and food allergies.

7. BlueWillow also developed and sold NanoBio® Protect, an over-the-counter nasal antiseptic that uses BlueWillow’s proprietary nanotechnology to deliver benzalkonium chloride (BZK), a common skin antiseptic that has been used in over-the-counter products for more than 75 years.

8. On February 10, 2021, Trutek filed suit alleging one count of patent infringement of the '802 Patent against BlueWillow.

9. Trutek's Complaint alleges that BlueWillow's NanoBio® Protect products directly infringe "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio® Protect] products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide."

10. The '802 patent is invalid and has not been and is not infringed by BlueWillow, directly (either literally or under the doctrine of equivalents), indirectly, contributorily, or by inducement.

**COUNT I:  
DECLARATORY JUDGMENT THAT BLUEWILLOW DOES NOT  
INFRINGE THE '802 PATENT**

11. BlueWillow repeats and re-alleges the allegations of paragraphs 1–10 as if fully set forth herein.

12. As a result of Trutek's assertions of infringement and filing suit against BlueWillow concerning the '802 Patent, an actual case or controversy exists with respect to the '802 Patent.

13. BlueWillow has not and does not, either literally or under the doctrine of equivalents, directly or indirectly infringe any valid and enforceable claim of the '802 Patent. For example, NanoBio® Protect does not restrict the flow of airborne contaminants or particulate matter into nasal passages and/or hold such airborne

contaminants or particulate matter outside the body, does not inactivate particulate matter, and does not prevent infection by electrostatically inhibiting harmful particulate matter, as required by the '802 Patent claims.

14. There is a substantial controversy between Trutek and BlueWillow concerning Trutek's claims of infringement of the '802 Patent that is of such immediacy and existence as to warrant a declaratory judgment.

15. Trutek's assertions of infringement of the '802 Patent, among other things, have directly and proximately injured BlueWillow and continues to injure BlueWillow.

16. BlueWillow's injuries would likely be redressed by a finding of non-infringement.

17. BlueWillow is entitled to a declaratory judgment that it has not infringed and is not infringing the '802 Patent.

**COUNT II:  
DECLARATORY JUDGMENT OF INVALIDITY OF THE '802 PATENT**

18. BlueWillow repeats and re-alleges the allegations of paragraphs 1–17 as if fully set forth herein.

19. All claims of the '802 Patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

20. For example, at least the following prior art references render each claim of the '802 Patent invalid under 35 U.S.C. § 102 and/or § 103: U.S. Patent No. 6,559,189; U.S. Patent No. 6,506,803; U.S. Patent No. 10,138,279; U.S. Published Application No. 2006/0163149; U.S. Published Application No. 2004/0071757; and U.S. Patent No. 5,468,488.

21. There is a substantial controversy between Trutek and BlueWillow about the invalidity of the '802 Patent by virtue of Trutek's claims of infringement by BlueWillow that is of such immediacy and existence as to warrant a declaratory judgment.

22. Trutek's assertions of infringement of invalid claims of the '802 Patent, among other things, has directly and proximately injured BlueWillow and continues to injure BlueWillow.

23. BlueWillow's injury would likely be redressed by a finding that the claims of the '802 Patent are invalid.

24. BlueWillow is entitled to a declaratory judgment that the claims of the '802 Patent are invalid.

### **RESERVATION OF RIGHTS AND OTHER DEFENSES**

BlueWillow expressly reserves the right to add any additional defenses or counterclaims that discovery may reveal.

### **PRAYER FOR RELIEF**

**WHEREFORE**, BlueWillow prays for a judgment against Trutek as follows:

- A. A judgment dismissing Trutek's Complaint with prejudice.
- B. A judgment providing that Trutek shall not be awarded any relief on its Complaint, including without limitation, any award of damages, attorneys' fees, costs or injunctive relief.
- C. A judgment declaring that BlueWillow does not infringe and has not infringed the '802 Patent.
- D. A judgment declaring each claim of the '802 Patent invalid.
- E. A judgment deeming this to be an exceptional case under 35 U.S.C. § 285 and awarding BlueWillow its attorney's fees.
- F. BlueWillow be awarded and recover the taxable costs of this civil action, including interest.
- G. Such other, further, and additional relief that may be considered just and equitable based on the facts and allegations contained herein or that arise in the course of the proceedings.

### **JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38(b), BlueWillow hereby demands a jury trial on all issues triable by a jury.

Respectfully submitted,

**FOLEY & LARDNER LLP**

Dated: May 19, 2021

*/s/ Alan J. Gocha*

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*Attorneys for Defendant/Counter-  
Plaintiff Blue Willow Biologics, Inc.*



**CERTIFICATE OF ELECTRONIC SERVICE**

I hereby certify that on May 19, 2021, I electronically filed this document, **DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIM, AND JURY DEMAND**, with the Clerk of the Court for the Eastern District of Michigan using the ECF System which will send notification to the registered participants of the ECF System as listed on the Court's Notice of Electronic Filing.

*/s/ Alan J. Gocha*

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